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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,021	10/14/2003	Charles William Rowe	MIT-AP-9-CON	4846

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EXAMINER	
WEBMAN, EDWARD J	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/685,021	**Applicant(s)** ROWE ET AL.	
	Examiner Edward J. Webman	**Art Unit** 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2007*.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.
  4a) Of the above claim(s) *3-5,12 and 17-24* is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1,2,6-11 and 13-16* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  a)☐ All b)☐ Some * c)☐ None of:
    1.☐ Certified copies of the priority documents have been received.
    2.☐ Certified copies of the priority documents have been received in Application No. _____.
    3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
  * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
  Paper No(s)/Mail Date *1/14/04*.
4) ☐ Interview Summary (PTO-413)
  Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's election of Group I, lactose, ethanol and methacrylate/methacrylic ester in the reply filed on 5/17/07 is acknowledged. Because applicant did not distinctly and specifically point out any errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant is correct, Group II should include claim 17.

The examiner adopts the rejection filed 6/13/03 in 09/904190 as directed to the instant claims:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6, 7, 9-11, and l4-16 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/36738 to Yoo et al.

Yoo et al. disclose a rapidly dispersing dosage form, which releases its active ingredients within a period of less than about ninety seconds. Yoo et al. teach that the unconventional dosage forms of their invention are built through an SFF process, such as 3DP (p 4, 1 27-28). Yoo et al. teach that the dosage form comprises a solid matrix incorporating at least one active ingredient, a bulk material and a binder, wherein the bulk material comprises at least one pharmaceutically acceptable compound in powder form, and the binder comprises a substantially water-soluble pharmaceutically acceptable substance that together with the powdered compound allows the matrix to maintain its three-dimensional structure in the absence of excess moisture (p 4, 1 2-9). Yoo et al. teach that the process involves spreading a layer of powder, then in selected regions adding the binder to the powder particles to form layers containing solid regions, the thickness of which varies as a function of binder properties and the amount of fluid applied per unit area (p 6, 1 25-30). This step is repeated until the desired number of layers for the dosage form is complete (p 7, 1 1-5). Yoo et al. further teach that the bulk powder material can be lactose, fructose, sucrose, dextrose, sorbitol, mannitol, xylitol, and microcrystalline cellulose (p 8, 1 18-20). Yoo et al. teach that the binder is essential to the invention, asit produces adhesion between the particles of the powder and the binder material. Yoo et al. teach that the binder can be a solvent for the bulk material or a further substance that is capable of bonding to particles of the bulk compound (p 8, 1 26-28). Furthermore, the binder may be included in either the powder material or in the fluid. Suitable binder material include, but are not limited to arabinogalactan, polyvinylpyrrolidone, sorbitol, mannitol, xylitol, and the like (p 9, 1 3-5). Yoo et al. also teach that a wide variety of substances can be used as the bulk material and the binder, including water- soluble synthetic polymers (p 11, 1 2-4). Yoo et al. also teach aqueous solutions of the binder material (p 15, 1 5,6).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 6-11, 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoo et al., as discussed above.

Yoo et al are described above as teaching a rapidly dispersing dosage form, made by the process of 3DP. Yoo et al further disclose that the composition used in the process comprises a bulk powder substance, a binder in solution, and a pharmaceutical agent.

Yoo et al does not refer to the ingredients employed in their composition and process by the same names used by applicant. However, it is the position of the examiner that the migration controlling agents claimed by applicant are actually well known binders in the pharmaceutical art (see below for further discussion). Therefore, the particular syntax used by applicant does not render the claims patentable.
Furthermore, Yoo et al. do not teach that the particle size of the migration control substance is less than 38 microns. However, it is the position of the examiner that absent a showing of criticality, the determination of a particular particle size is a manipulatable parameter as part of the process of optimization for one of ordinary skill in the art. Any unexpected results must be dependant on the particle size in order to show criticality for this particular limitation.

Additionally, Yoo et al. do not specifically teach that the migration control substance is methacrylate or methacrylic ester copolymer. However, it is the position of the examiner that the substances claimed by applicant as migration control substances are all well known binders in the pharmaceutical art. Furthermore, it is the position of the examiner that methacrylates are well known in the art as acceptable pharmaceutical binders. However, to reiterate this point, the examiner points to International Cosmetic Ingredient Dictionary and Handbook (Attached) which gives a list of acceptable binders. Acrylates, as well as celluloses, polyvinylpyrrolidone, xanthan gum, locust bean gum, gelatin, guar gum, and others, are all listed as appropriate binders. It is the position of the examiner that this disclosure shows equivalency between the listed compounds. Therefore, one of ordinary skill in the art would have been motivated to use any well known binder, or combination of binders in the teachings of Yoo et al. The motivation lies in the teaching of equivalency. The expected result would be a successful rapidly dispersing dosage form, as taught by Yoo et al.

Lastly, Yoo et al does not specifically state a method of controlling binder migration. However, it is the position of the examiner again that this in only a syntax differentiation. As stated above, it is the position of the examiner that the migration controlling substances claimed by applicant are known in the pharmaceutical art by another name, binders. Yoo et al. specifically state that the binder is an essential element of the invention, as it produces adhesion between particles of the powder and binder material (p 8, 1 21-22). In other words, the binder prevents binder migration. Furthermore, Yoo et al. teach that the fluid used in the composition and process is a pharmaceutically acceptable solvent or combination of solvents, and may contain one or more binders and actives. It is the position of the examiner that Yoo et al. does teach a method of controlling migration, except it is not referred to by the same name. For these reasons, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Richter, can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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